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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/840,439	07/21/2010	Lutz BARNSCHEID	107101-77 KGB	1148

27386 7590 12/05/2016

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ART UNIT	PAPER NUMBER
1619	

MAIL DATE	DELIVERY MODE
12/05/2016	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte LUTZ BARNSCHEID and ERIC GALIA[1,2]

Appeal 2014-005206
Application 12/840,439
Technology Center 1600

Before ERIC B. GRIMES, ULRIKE W. JENKS, and
RACHEL H. TOWNSEND, *Administrative Patent Judges*.

TOWNSEND, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a hot-melt extruded dosage form dosage form, which have been rejected as anticipated. We have jurisdiction under 35 U.S.C. § 6(b).

We affirm.

STATEMENT OF THE CASE

"With controlled release tablets care has to be taken that under no circumstances the pharmaceutically active ingredient will be released completely and instantaneously in an uncontrolled manner." (Spec. 1.)

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[1] Appellants identify the Real Party in Interest as Grünenthal GmbH. (Appeal Br. 1.)
[2] An oral argument was held on November 29, 2016.

Pharmaceutical dosage forms having an increased breaking strength are "useful for avoiding drug abuse of the pharmacologically active compound contained therein" (Spec. 2) and "may also exhibit a certain degree of controlled release of the pharmacologically active compound contained therein" (Spec. 1). However, "there is a demand for tamper resistant pharmaceutical dosage forms the release profile of which may be varied within certain limits without diminishing the tamper resistance, without substantially changing the nature or amount of the pharmaceutical excipients, and without deteriorating the compliance of the pharmaceutical dosage form" (Spec. 5.) Appellants' invention is directed to such a dosage form. (Spec. 1 and 5.)

Claims 1–9 and 14 are on appeal. Claim 1 is representative and reads as follows:

1. A hot-melt extruded pharmaceutical dosage form with controlled release of a pharmacologically active ingredient (A) embedded in a matrix comprising a polymer (C), the dosage form exhibiting a breaking strength of at least 300 N and having an oblong shape comprising a longitudinal direction of extension, a transversal direction of extension orthogonal to the longitudinal direction of extension, a front side, an opposite back side and a circumferential rim between said front and back sides;

wherein

- the core of the pharmaceutical dosage form has a morphological orientation caused by hot-melt extrusion that is substantially orthogonal to the longitudinal direction of extension of the dosage form; or

- the release per unit area of the pharmacologically active ingredient (A) through the front side and the opposite back side is faster than the release through the circumferential rim.

(Appeal Br. 15.)

The following grounds of rejection by the Examiner are before us on review:

Claims 1–9 and 14 under 35 U.S.C. § 102(b) as anticipated by Ashworth.[3]

Claims 1–9 and 14, provisionally, on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 4, 5, and 9 of copending Application 13/223358 in view of Ashworth.

Claims 1–9 and 14, provisionally, on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 9, 10, and 13 of copending Application No. 13/223384 in view of Ashworth.

DISCUSSION

Anticipation

The Examiner finds that Ashworth teaches a hot melt extruded dosage form with an active ingredient embedded in a polymer matrix where the

[3] Ashworth et al., US 2006/0193914 A1, published Aug. 31, 2006.

shape of the dosage form can be oblong and where the dosage form exhibits a breaking strength of at least 300 N. (Final Action 3; Ans. 2–3 and 18–19.) The Examiner further finds that the core of the dosage form having an oblong shape would have the morphological orientation claimed. (*Id.*)

We agree with the Examiner's factual findings and conclusion that Ashworth teaches an oblong dosage form that has the morphological orientation claimed.

We agree with the Examiner (Final Action 3; Ans. 2) that Ashworth teaches that the die geometry of a hot melt extruder could include bores that may exhibit oblong geometry. (Ashworth ¶ 194.) Moreover, Ashworth teaches that the extrudate may be cut into individual units having the desired tablet weight, *i.e.*, singulated. (Ashworth ¶¶ 195 and 358.) According to Ashworth, the crush resistance of at least 400 N may be established by the force applied in the extrusion process. (Ashworth ¶ 199.) Thus, we agree with the Examiner that Ashworth teaches a dosage form having the requisite oblong shape and breaking strength, regardless of whether a tableting tool might determine "the *final* shape of the dosage form" (Reply Br. 4 (emphasis added)).

We further agree with the Examiner that Ashworth's Figure 5B is a general teaching of the morphological orientation of the core of a tablet and the surrounding tubular domain obtained from the hot melt extrusion process. (Ans. 14; Ashworth ¶¶ 263, 275, 278 and ¶¶ 178, 182–184, 191–195.) There is no dispute that the depicted singulated form in Figure 5B is a circular tablet. However, there is no indication that this arrangement of the tubular domain and core within the dosage form is altered in any way by the

use of an extrusion die with an oblong bore. Indeed, as Appellants point out, Ashworth explains in paragraph 265 that "'[u]sually the extrusion skin covers the entire shell of the extrudate like a one-piece collar, ***independently*** of what geometry has been chosen for the extrusion die (emphasis added).'" (Reply Br. 5.) In other words, the core morphology will be the same as in Figure 5B, even if an oblong die is used. That is true regardless of the length of the singulated oblong extrudate, *i.e.*, the oblong cross-section, would remain orthogonal to the longitudinal direction of extension regarless of the length of the singulated oblong extrudate. Consequently, we agree with the Examiner that Figure 5B is applicable with respect to the depiction of the morphological orientation of a singulated hot melt extruded material whether the die used was circular, oblong, or even oval. Thus, for this reason we also agree with the Examiner that Ashworth teaches the morphological orientation claimed.

It is only with the "conventional manufacture" described in paragraphs 11–14 of the inventor Barnscheid's declaration[4] that the morphological orientation differs from what is claimed, *i.e.*, when a cylindrical extrudate of a certain length is press formed along its length into an oblong tablet. However, Ashworth teaches that the breaking strength of at least 400 N is achieved through the extrusion process. Nothing in the claim requires pressing the singulated material into a tablet. All that is required is a controlled release composition in an oblong shape made by hot melt extrusion that includes a pharmaceutically active ingredient embedded

[4] Declaration of Dr. Lutz Barnscheid dated Nov. 27, 2012.

in a polymer matrix that has a particular minimum breaking strength and a particular morphological orientation. We find that a singulated oblong extrudate of Ashworth, prior to any additional shaping (Reply Br. 2–3), meets the requirements of claim 1.

Appellants argue that the Examiner has engaged in improper "picking, choosing and combining" in the anticipation rejection and has conveniently ignored the "oblong embodiment" depicted in Figure 5A of Ashworth. (Appeal Br. 6–8.) We disagree. As to Figure 5A, the Examiner noted (Ans. 16–18) that there is nothing in Ashworth indicating that Figures 5A and 5B are intended to show the difference between an oval embodiment and a circular embodiment. While it is possible, as indicated in the Barnscheid Declaration (¶¶11–14 and Figure 2), that the depicted extrudate in Figure 5A of Ashworth could be molded into an oval tablet through a conventional manufacturing process, Figure 5A could also simply be a depiction of the cylindrical extrudate as it exits the extruder and prior to singulation. All that Ashworth itself indicates with respect to Figure 5A is that, like Figure 5B, it is a schematic depiction of the morphology of the tubular arrangement of the extrusion skin surrounding the core of the extrudate within the dosage form. (Ashworth ¶¶ 263–64 and 275.) Thus, while Figure 5A might show the cylindrical core 83 running parallel to the long axis of the dosage form *should that be further* shaped into an oval form with conventional manufacturing, there is no indication in Ashworth that such manufacturing is carried out on the material depicted. Figure 5A simply depicts an extrudate that, because it was made according to the teachings of Ashworth's process,

would have a breaking strength of greater than 400 N, and like Figure 5B, has a core that is perpendicular to the diameter of the circular cross section.

Furthermore, the rejection by the Examiner does not combine selected elements from disparate embodiments to find anticipation, which we agree would be improper, *see e.g.*, *Net MoneyIN, Inc. v. Verisign, Inc.,* 545 F.3d 1359, 1371 (Fed. Cir. 2008). It is irrelevant that Ashworth's paragraph 194 does not reference Figure 5B (Appeal Br. 8) or otherwise show an oblong form (Appeal Br. 9), because there is no requirement that a disclosed embodiment be depicted in a figure to demonstrate anticipation. Nor is there any requirement that an inherent feature, such as morphological orientation, be depicted in a reference for the reference to anticipate. We also find it irrelevant that Ashworth indicates the bores are "freely selectable" (Appeal Br. 8). Ashworth specifically notes that

> The die or the bores may accordingly exhibit a round, oblong or oval cross-section, wherein the round cross-section preferably has a diameter of 0.1 mm to 15 mm and the oblong cross-section preferably has a maximum lengthwise extension of 21 mm and a crosswise extension of 10 mm.

(Ashworth ¶ 194.) We conclude that Ashworth discloses a small genus of extrudate shapes that have the claimed breaking strength (Ashworth ¶ 199), and when singulated as is taught to be preferable (Ashworth ¶ 195), would have the morphological orientation claimed. Thus, the Examiner's anticipation rejection is proper because the disclosure of Ashworth allows one skilled in the art to "at once envisage each member of the limited class"

including the specifically mentioned oblong cross-section. *In re Petering*, 301 F.2d 676, 681–82 (CCPA 1962).[5]

We also disagree with Appellants that the Examiner improperly ignored the Declaration of Dr. Barnscheid. (Appeal Br. 9–11.) The Examiner explained that Dr. Barnscheid's discussion of conventional manufacturing of oblong tablets was not relevant in light of Ashworth's teachings of making an oblong shaped extrudate and singulating such an extrudate and he ignored the general depiction of the morphological orientation of singulated extrudate depicted in Figure 5B which demonstrated that singulated forms that were oblong would also inherently have the claimed morphological orientation. (Final Action 6–7; Ans. 25–27.) We do not find error with the Examiner's assessment. Moreover, we also do not find persuasive Appellants' point that Ashworth does not teach or suggest "that in the context of oblong tablets the positioning of the extrudate on the tabletting tool determines the release properties of the resulting dosage form" (Appeal Br. 10) because the release properties recited in claim 1 are not a necessary limitation: Claim 1 requires a particular

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[5] We do not find *Sanofi-Synthelabo v. Apotex Inc.,* 550 F.3d 1075 (Fed. Cir. 2008), cited by Appellants (Appeal Br. 8–9, Reply Br. 5–6) relevant. The claimed separated dextrorotary enantiomer in that case was found not to be anticipated by disclosure of the racemate because the prior art reference itself did not disclose any separated enantiomers or describe how to separate them and there was evidence of record that separating enantiomers at the relevant time period was difficult, and that other racemates of related compounds disclosed in the prior art that were separated into their enantiomers did not demonstrate advantage over the racemate. 550 F.3d 1075, 1083–84. Here, Ashworth describes the oval shape and there is no indication in the record that forming such an extruded shape was difficult.

morphological orientation "or" that "the release per unit area of the pharmacologically active ingredient (A) through the front side and the opposite back side is faster than the release through the circumferential rim" (Appeal Br. 15 (claim 1)), not both.

Appellants contend that they have provided evidence of unexpected results demonstrating the criticality of the orientation of the extrudate on the tablet press, and have shown it to be a result-effective-variable determining the release properties of the dosage form that cannot be ignored even if this is an anticipation rejection, citing *e.g.*, *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991 (Fed. Cir. 2006). (Appeal Br. 11–12; Reply Br. 6.) However, for the reasons discussed above, we agree with the Examiner that Ashworth provides for a small genus of tablets having the claimed morphological orientation and breaking strength, and thus, anticipates the claimed dosage form. The orientation of a singulated oval extrudate (a cross-section shape specifically disclosed in the small genus of die shapes identified in Ashworth (¶ 194)) has the claimed morphological orientation and the extrudate has the claimed breaking strength. Thus, the Examiner is correct in stating that secondary considerations of non-obviousness cannot be used for the anticipation rejection here (Ans. 28–29). *See Seachange Int'l, Inc. v. C-COR, Inc.* 413 F.3d 1361, 1380 (Fed. Cir. 2005) ("Teaching away is irrelevant to anticipation"); *WL Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F. 2d 1540 (Fed. Cir. 1983) (DAVIS, Circuit Judge, concurring in the result in part and dissenting in part) ("discussion of 'secondary considerations,'. . . is irrelevant to the issue of anticipation"). Moreover, whether Ashworth

demonstrates placing the claimed oriented extrudate on a tablet press is not relevant as that is not a limitation of the claimed dosage form.

For the reasons discussed, Appellants do not persuade us that the Examiner erred in rejecting claim 1 for anticipation over Ashworth. Accordingly, we affirm the Examiner's rejection of independent claim 1.

Claims 2–9 and 14 have not been argued separately and, therefore, fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

Provisional Rejections

In each of the provisional obviousness-double patenting rejections, the Examiner relies on Ashworth for teaching the morphological limitation missing in the copending application claims. (Final Action 9 and 11.) Appellants argue that the Examiner's rejection is in error because "Ashworth does not, in fact, teach the morphological limitations of instant claim 1." (Appeal Br. 12 and 13.) However, for the reasons discussed above we do not find Appellants' argument on that score persuasive. Accordingly, we affirm both of the Examiner's provisional nonstatutory obviousness-type double patenting rejections.

SUMMARY

We affirm the rejection of claims 1–9 and 14 under 35 U.S.C. § 102(b) as anticipated by Ashworth.

We affirm the provisional rejection of claims 1–9 and 14 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 3, 4, 5, and 9 of copending Application 13/223358 in view of Ashworth.

We affirm the provisional rejection of claims 1–9 and 14 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 9, 10, and 13 of copending Application No. 13/223384 in view of Ashworth.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED